

Atty Dkt No. 3100-0003
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Jenny LOUIE-HELM et al.

Confirmation No.: 1055

Serial No.: 10/014,750

Group Art Unit: 1615

Filing Date: October 25, 2001

Examiner: Blessing M. Fubara

Title: FORMULATION OF AN ERODIBLE, GASTRIC RETENTIVE ORAL DOSAGE FORM
USING IN VITRO DISINTEGRATION TEST DATA

RESUBMITTED INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia

Sir:

Further to the Examiner's request in the Office Action of August 21, 2003, the Information Disclosure Statement of April 4, 2003, is resubmitted per the Examiner's request. In the Office Action, the Examiner indicated that the cited references were not available to the Examiner. As the cited references are provided with this paper, applicants respectfully request that the Examiner review and make of record the references identified below.

A PTO-1449 form listing the cited references is also resubmitted for the Examiner's convenience and is attached to this paper. Upon review of the references submitted herewith, applicants respectfully request that the Examiner initial and return a copy of the PTO-1449 to the applicants in order so that applicants will have a written record that the references submitted herewith have been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
4,434,153	2/28/84	Urquhart et al.
4,690,824	9/1/87	Powell et al.
4,748,023	5/31/88	Tamás et al.
4,786,503	11/22/88	Edgren et al.
4,839,177	6/13/89	Colombo et al.
4,851,232	7/25/89	Urquhart et al.
4,865,849	9/12/89	Conte et al.
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Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
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5,232,704	8/3/93	Franz et al.
5,393,765	2/28/95	Infeld et al.
5,422,123	6/6/95	Conte et al.
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5,487,901	1/30/96	Conte et al.
5,508,040	4/16/96	Chen
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5,681,583	10/28/97	Conte et al.
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5,916,595	6/29/99	Chen et al.
6,033,685	3/7/00	Qiu et al.
6,207,197	3/27/01	Illum et al.
6,261,601	7/17/01	Talwar et al.
6,340,475	01/22/02	Shell et al.
6,368,628	4/9/02	Seth
6,451,808	9/17/02	Cowles
6,488,962	12/3/02	Berner et al.
2001/0018070	8/30/01	Shell et al.
Serial No. 09/425,491	Filed 10/22/99	Shell et al.
Serial No. 10/029,134	Filed 10/25/01	Gusler et al.
Serial No. 10/045,823	Filed 11/6/01	Shell et al.
Serial No. 10/066,146	Filed 2/1/02	Lim et al.
Serial No. 10/152,914	Filed 5/20/02	Fara et al.
Serial No. 10/280,309	Filed 10/25/02	Berner et al.
Serial No. 10/280,852	Filed 10/25/02	Devane et al.

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Apicella et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release," <i>Biomaterials</i> <u>14</u> (2):83-90.
Baumgartner et al. (2000), "Optimisation of Floating Matrix Tablets and Evaluation of Their Gastric Residence Time," <i>International Journal of Pharmaceutics</i> <u>195</u> :125-135.
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Columbo et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," <i>International Journal of Pharmaceutics</i> <u>63</u> :43-48.
Davis et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> <u>3</u> (4):208-213.
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Ford et al. (1987), "Importance of Drug Type, Tablet Shape and Added Diluents on Drug Release Kinetics from Hydroxypropylmethylcellulose Matrix Tablets," <i>International Journal of Pharmaceutics</i> <u>40</u> :223-234.
Gao et al. (1996), "Swelling of Hydroxypropyl Methylcellulose Matrix Tablets. 2. Mechanistic Study of the Influence of Formulation Variables on Matrix Performance and Drug Release," <i>Journal of Pharmaceutical Sciences</i> <u>85</u> (7):732-740.
Hwang et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> <u>15</u> (3):243-284.
Ju et al. (1995), "Drug Release from Hydrophilic Matrices. 1. New Scaling Laws for Predicting Polymer and Drug Release Based on the Polymer Disentanglement Concentration and the Diffusion Layer," <i>Journal of Pharmaceutical Sciences</i> <u>84</u> (12):1455-1463.
Ju et al. (1995), "Drug Release from Hydrophilic Matrices. 2. A Mathematical Model Based on the Polymer Disentanglement Concentration and the Diffusion Layer," <i>Journal of Pharmaceutical Sciences</i> <u>84</u> (12):1464-1477.
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Lapidus et al. (1966), "Some Factors Affecting the Release of a Water-Soluble Drug from a Compressed Hydrophilic Matrix," <i>Journal of Pharmaceutical Sciences</i> <u>55</u> (8):840-843.
Lapidus et al. (1968), "Drug Release from Compressed Hydrophilic Matrices," <i>Journal of Pharmaceutical Sciences</i> <u>57</u> (8):1292-1301.
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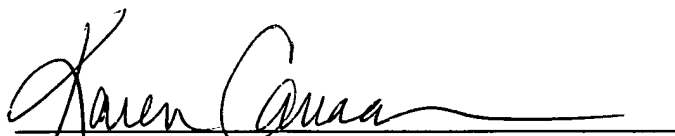
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Maggi et al. (2000), "Highly Swellable Multi-Layer Tablets to Prolong the Residence Time of the Delivery in the Stomach," <i>Journal of Controlled Release</i> 64:269-347.
Oth et al. (1992), "The Bilayer Floating Capsule: A Stomach-Directed Drug Delivery System for Misoprostol," <i>Pharmaceutical Research</i> 9(3):298-302.
Rao et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> 48:1-13.
Reynolds et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> 87(9):1115-1123.
Shameem et al. (1995), "Oral Solid Controlled Release Dosage Forms: Role of GI-Mechanical Destructive Forces and Colonic Release in Drug Absorption Under Fasted and Fed Conditions in Humans," <i>Pharmaceutical Research</i> 12(7):1049-1054.
Siepmann et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> 16(11):1748-1756.
Yang et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> 85(2):170-173.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

The attached return post-card indicates that the cited references were mailed along with the Information Disclosure Statement and PTO-1449 on April 4, 2003; accordingly, applicants submit that this resubmission of the Information Disclosure Statement of April 4, 2003, should not be subject to a fee. Nevertheless, if the Office deems that a fee is necessary, then the Office is authorized to charge the appropriate fee to Deposit Account No. 18-0580.

Respectfully submitted,

By:


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Registration No. 42,382

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/014,750
Filing Date	October 25, 2001
First Named Inventor	Jenny LOUIE-HELM et al.
Art Unit	1615
Examiner Name	Blessing M. Fubara
Attorney Docket Number	3100-0003

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
	AY	4,434,153	2/28/84	Urquhart et al.			
	AZ	4,690,824	9/1/87	Powell et al.			
	BA	4,748,023	5/31/88	Tamás et al.			
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	BC	4,839,177	6/13/89	Colombo et al.			
	BD	4,851,232	7/25/89	Urquhart et al.			
	BE	4,865,849	9/12/89	Conte et al.			
	BF	5,064,656	11/12/91	Gergely et al.			
	BG	5,085,865	2/4/92	Nayak			
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	BK	5,422,123	6/6/95	Conte et al.			
	BL	5,458,887	10/17/95	Chen et al.			
	BM	5,458,888	10/17/95	Chen			
	BN	5,464,633	11/7/95	Conte et al.			
	BO	5,472,708	12/5/95	Chen			
	BP	5,487,901	1/30/96	Conte et al.			
	BQ	5,508,040	4/16/96	Chen			
	BR	5,549,913	8/27/96	Colombo et al.			
	BS	5,609,590	3/11/97	Herbig et al.			
	BT	5,626,874	5/6/97	Conte et al.			
	BU	5,650,169	7/22/97	Conte et al.			
	BV	5,651,985	7/29/97	Penners et al.			
	BW	5,681,583	10/28/97	Conte et al.			
	BX	5,688,776	11/18/97	Bauer et al.			
	BY	5,736,159	4/7/98	Chen et al.			
	BZ	5,780,057	7/14/98	Conte et al.			
	CA	5,811,126	9/22/98	Krishnamurthy			
	CB	5,837,379	11/17/98	Chen et al.			
	CC	5,840,329	11/24/98	Bai			
	CD	5,897,874	4/27/99	Stevens et al.			
	CE	5,916,595	6/29/99	Chen et al.			
	CF	6,033,685	3/7/00	Qiu et al.			
	CG	6,207,197	3/27/01	Illum et al.			
	CH	6,261,601	7/17/01	Talwar et al.			
	CI	6,340,475	01/22/02	Shell et al.			
	CJ	6,368,628	4/9/02	Seth			5/26/00
	CK	6,451,808	9/17/02	Cowles			10/17/00
	CL	6,488,962	12/3/02	Berner et al.			6/20/00

Examiner Signature	Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 3

Complete if Known

Application Number	10/014,750
Filing Date	October 25, 2001
First Named Inventor	Jenny LOUIE-HELM et al.
Art Unit	1615
Examiner Name	Blessing M. Fubara
Attorney Docket Number	3100-0003

	CM	2001/0018070	8/30/01	Shell et al.			
	CN	Serial No. 09/425,491		Shell et al.			10/22/99
	CO	Serial No. 10/029,134		Gusler et al.			10/25/01
	CP	Serial No. 10/045,823		Shell et al.			11/6/01
	CQ	Serial No. 10/066,146		Lim et al.			2/1/02
	CR	Serial No. 10/152,914		Fara et al.			5/20/02
	CS	Serial No. 10/280,309		Berner et al.			10/25/02
	CT	Serial No. 10/280,852		Devane et al.			10/25/02

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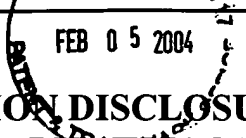
Examiner Initials*	Cite No.	Foreign Patent Document No.	Publication Date	Country	Class	Subclass	T
	CU	EP 0598309 B1	1/28/98	Europe			
	CV	EP 0795324 A2	9/17/97	Europe			
	CW	GB 1330829	9/19/73	United Kingdom			
	CX	WO 96/32097 A1	10/17/96	PCT			
	CY	WO 98/55107 A1	12/10/98	PCT			
	CZ	WO 00/23045 A1	4/27/00	PCT			
	DA	WO 00/38650 A1	7/6/00	PCT			
	DB	WO 01/32217 A3	5/10/01	PCT			
	DC	WO 01/56544 A3	8/9/01	PCT			
	DD	WO 01/97783 A1	12/27/01	PCT			
	DE	WO 02/083687 A1	10/24/02	PCT			

OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	DF	Abrahamsson, et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.	
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	DK	Columbo et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," <i>International Journal of Pharmaceutics</i> 63:43-48.	
	DL	Davis et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> 3(4):208-213.	
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Examiner Signature	Date Considered
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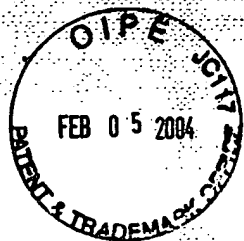
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Sheet	3	of	3	Attorney Docket Number		3100-0003

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	DO	Gao et al. (1996), "Swelling of Hydroxypropyl Methylcellulose Matrix Tablets. 2. Mechanistic Study of the Influence of Formulation Variables on Matrix Performance and Drug Release," <i>Journal of Pharmaceutical Sciences</i> 85(7):732-740.	
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4-4-03 kmo
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Attorney Docket No.: 3100-0003 Mailing Date: April 4, 2003

Inventor(s): Jenny Louie-Helm et al.

Serial No.: 10/014,750 Filing Date: 10/25/2001

Document(s):
Supplemental Information Disclosure (5 pages)
PTO Form 1449 (3 pages)
Copies of Cited References
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April 4, 2003

10/25/2001

(5 pages)



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